Message

From: Heather Blankinship [hblankinship@bc-cm.com]

Sent: 6/4/2021 1:10:30 AM

To: Turk, David [Turk.David@epa.gov]

CC: Henry, Tala [Henry.Tala@epa.gov]; Hartman, Mark [Hartman.Mark@epa.gov]; Richard E. Engler, Ph.D.

[rengler@lawbc.com]; lbergeson@lawbc.com; Widawsky, David [Widawsky.David@epa.gov]; Reisman, Larry

[Reisman.Larry@epa.gov]; Lee, Virginia [Lee.Virginia@epa.gov]; Clark, Sarah E. [clark.sarahe@epa.gov]

Subject: RE: TDCE Consortium - EPA Comments on Initial Study Plans for Section 4 Test Order

David:

Thank you for confirming.

HEATHER BLANKINSHIP SENIOR MANAGER

B&C® CONSORTIA MANAGEMENT LLC

2200 Pennsylvania Avenue, NW, Suite 100W| Washington, DC 20037 T: 202-557-3831 | F: 202-557-3836 | bc-cm.com

From: Turk, David <Turk.David@epa.gov> Sent: Thursday, June 3, 2021 5:11 PM

To: Heather Blankinship hblankinship@bc-cm.com

Cc: Henry, Tala < Henry. Tala@epa.gov>; Hartman, Mark < Hartman.Mark@epa.gov>; Richard E. Engler, Ph.D. < rengler@lawbc.com>; Lynn L. Bergeson < lbergeson@lawbc.com>; Widawsky, David < Widawsky.David@epa.gov>; Reisman, Larry < Reisman, Larry @epa.gov>; Lee, Virginia < Lee. Virginia@epa.gov>; Clark, Sarah E.

<clark.sarahe@epa.gov>

Subject: [EXTERNAL] RE: TDCE Consortium - EPA Comments on Initial Study Plans for Section 4 Test Order

This is to confirm that EPA will revise the deadline for the final study plan when we finish reviewing the draft study plans. Final study plans are not due today.

From: Heather Blankinship hblankinship@bc-cm.com

Sent: Thursday, June 3, 2021 10:17 AM To: Turk, David < Turk. David@epa.gov>

Cc: Henry, Tala Hertman, Mark @epa.gov> ; Reisman, Larry@epa.gov> ; Reisman, Larry@epa.gov> ; Lee, Virginia Lee, Virginia@epa.gov> ; Clark, Sarah E. Lee, Virginia@epa.gov> ; Clark, Sarah E. Lee, Virginia@epa.gov> ; Clark, Sarah E. Lee.Virginia@epa.gov> ; Clark, Sarah E. Lee.Virginia@epa.gov ; Clark, Sarah E. Lee.Virginia@epa.gov ; Clark, Sarah C. Lee.Virginia@epa.gov ; Clark, Sarah C. <a

Subject: RE: TDCE Consortium - EPA Comments on Initial Study Plans for Section 4 Test Order

David:

Please confirm that:

- The TDCE Consortium is not obligated to submit final study plans **today**, **June 3**, **2021**, for the *in vitro* dermal absorption and occupational inhalation exposure studies; and
- The Consortium is being granted an extension for submitting the final study plans, pending the U.S.
 Environmental Protection Agency's (EPA) review of and the Consortium's receipt of EPA's comments on the initial study plans.

HEATHER BLANKINSHIP SENIOR MANAGER

B&C® CONSORTIA MANAGEMENT LLC

From: Turk, David < Turk. David@epa.gov > Sent: Wednesday, June 2, 2021 4:50 PM

To: Heather Blankinship hblankinship@bc-cm.com; Clark, Sarah E. <clark.sarahe@epa.gov>

Cc: Henry, Tala Henry, Tala @epa.gov>; Hartman, Mark Hartman. Mark @epa.gov>; Richard E. Engler, Ph.D.

<rengler@lawbc.com>; Lynn L. Bergeson < bergeson@lawbc.com>; Widawsky, David < Widawsky.David@epa.gov>;

Reisman, Larry < Reisman. Larry@epa.gov>; Lee, Virginia < Lee. Virginia@epa.gov>

Subject: [EXTERNAL] RE: TDCE Consortium - EPA Comments on Initial Study Plans for Section 4 Test Order

Heather,

Thank you for your message and for checking in on the status of the draft study plans. Note that contrary to your assertion, EPA not having yet responded to a given submission does not equate to approval of a draft study plan. EPA is continuing to review the draft study plans that it has received.

EPA will respond to each draft study plan and provide a revised deadline for the final study plan at that time, providing a reasonable amount of time for the consortium/recipient to consider EPA's response.

-Dave, Data Collection Branch

From: Heather Blankinship hblankinship@bc-cm.com

Sent: Tuesday, June 1, 2021 8:32 AM

To: Clark, Sarah E. <clark.sarahe@epa.gov>

Cc: Turk, David < Turk. David@epa.gov>; Henry, Tala < Henry. Tala@epa.gov>; Hartman, Mark < Hartman. Mark@epa.gov>;

Richard E. Engler, Ph.D. <rengler@lawbc.com>; |bergeson@lawbc.com

Subject: TDCE Consortium - EPA Comments on Initial Study Plans for Section 4 Test Order

Sarah:

B&C® Consortia Management, L.L.C. (BCCM) notes that it submitted to the U.S. Environmental Protection Agency (EPA), on behalf of the TDCE Consortium (the Consortium), initial study plans for the following studies required by the Toxic Substances Control Act (TSCA) Section 4 Test Order for *trans*-1,2-dichloroethylene (TDCE):

- In Vitro Dermal Absorption Study -- submitted April 2, 2021; and
- Occupational Inhalation Exposure Study -- submitted May 14, 2021.

The deadline to submit final study plans for both of these studies is **June 3, 2021**, and EPA has not yet responded with approval of the plans or suggested changes. The Consortium is concerned that it will not be able to adapt its study plans, as needed, to address EPA's comments and submit timely the final study plans.

On **June 2, 2021**, the Consortium will consider EPA's lack of response as acceptance of the initial study plans, and the Consortium will submit the initial study plans as final on **June 3, 2021**. If it is not EPA's intent that its lack of response be viewed as acceptance of the initial study plans, the Consortium requests an extension of a minimum of two weeks from the date it receives EPA's comments to submit final study plans. This is necessary to provide the Consortium sufficient time to work with its members to address EPA's comments.

HEATHER BLANKINSHIP SENIOR MANAGER

B&C® CONSORTIA MANAGEMENT LLC

2200 Pennsylvania Avenue, NW, Suite 100W| Washington, DC 20037 T: 202-557-3831 | F: 202-557-3836 | be-cm.com